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MEDICAL DEVICE DESIGN QUALITY

1.1 INTRODUCTION

Throughout the evolution of quality, there has always been a preponderance of focus on the manufacture of parts. In recent years, more applications have focused on design in general; however, the application of a full suite of tools to medical device design is rare and still considered risky or challenging. Some companies in the medical industry that have mature six sigma deployment programs see the application of design for six sigma to product and internal processes as an investment rather than a needless expense.

Attention has begun to shift from improvement of design quality in downstream development stages to early upstream stages. This shift is motivated by the fact that design decisions made during early stages of the product development cycle have the greatest impact on total life-cycle cost and system quality. It has been claimed that as much as 80% of the total life-cycle cost is determined during the concept development stage (Fredrikson, 1994). The deployment of design for six sigma in the device development and manufacturing arenas is currently experiencing an increased focus on addressing industry efforts to shorten lead times, cut development and manufacturing costs, lower total life-cycle cost, and improve device quality. It is the author's experience that at least 80% of a design's quality is also determined in the early design phases.

Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness,
By Basem S. El-Haik and Khalid S. Mekki

As mentioned in the Preface, design vulnerabilities are the result of poor quality and design engineering practices. In the context of *design for six sigma* (DFSS), the major design vulnerabilities are categorized as follows:

- Conceptual vulnerabilities based on the violation of design principles (for examples of design principles, see Chapters 9 to 12).
- Operational vulnerabilities created as a result of factors beyond the control of designers, called *noise factors*. Such factors are, in general, responsible for causing a device's functional characteristic or process to deviate from target values. Controlling noise factors is very costly or difficult, if not impossible. Operational vulnerability is usually addressed by robust design (see Chapters 15 and 16) (Taguchi et al., 1989).

In medical device design, conceptual vulnerabilities will always result in operational vulnerabilities. However, the reverse is not true. That is, it is possible for a healthy device concept that is in full obedience to design principles to be operationally vulnerable. In this book we are addressing the two categories of design vulnerability.

Profitability is one of the most important factors for any successful business enterprise. High profitability is determined by strong sales and overall low cost in all company operations. Healthy sales are determined strongly by high quality and reasonable price; as a result, improving quality and reducing cost are among the most important tasks for any business enterprise. Six sigma and DFSS are new business excellence initiatives that would effectively reduce cost and improve quality. In medical device design, quality and safety are interlinked. Most errors and inefficiencies in patient care arise from conflicting, incomplete, or suboptimal devices.

The objective of DFSS is to design and redesign medical devices to make them safer and more effective, patient centered, timely, and efficient. How does one achieve quality and safety by quality? What is quality?

1.2 THE ESSENCE OF QUALITY

Quality is a more intriguing concept than it appears to be. The meaning of the term *quality* has evolved over time as many concepts were developed to improve product or service quality, including total quality management (TQM), the Malcolm Baldrige National Quality Award, six sigma, quality circles, the theory of constraints quality management systems [ISO 9000 and ISO 13485], axiomatic quality (El-Haik, 2005), and continuous improvement. Following are various interpretations of quality:

- "Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance" [21 CFR 820.3(s)].

- "Quality: an inherent or distinguishing characteristic, a degree or grade of excellence" (*American Heritage Dictionary*, 1996).
- "Quality and the required style of management" (W. Edwards Deming).
- "Conformance to requirements" (Philip B. Crosby in the 1980s).
- "Fitness for use" (Joseph M. Juran).
- "Degree to which a set of inherent characteristic fulfills requirements" (ISO 9000).
- "Value to some person" (Gerald M. Weinberg).
- "The loss a product imposes on society after it is shipped" (Genichi Taguchi).
- "The degree to which the design vulnerabilities do not adversely affect product performance" (Basem El-Haik).

Quality is a characteristic that a product or service must have. It refers to the perception of the degree to which a product or service meets a customer's expectations. Quality has no specific meaning unless it is related to a specific function or measurable characteristic. The dimensions of quality refer to the measurable characteristics that quality achieves. For example, in the design and development of a medical device:

- Quality supports safety and performance.
- Safety and performance support durability.
- Durability supports flexibility.
- Flexibility supports speed.
- Speed supports cost.

You can easily build the interrelationship between quality and all aspects of product characteristics, as these characteristics act as the qualities of the product. However, not all qualities are equal. Some are more important than others. The most important qualities are the ones that customers want most. These are the qualities that products and services must have. So providing quality products and services is all about meeting customer requirements. It's all about meeting the needs and expectations of customers.

When the word *quality* is used, we usually think in terms of an excellent design or service that fulfils or exceeds our expectations. When a product design surpasses our expectations, we consider that its quality is good. Thus, quality is related to perception. Conceptually, quality can be quantified as follows (Yang and El-Haik, 2003):

$$Q = \frac{\sum P}{\sum E} \tag{1.1}$$

where Q is quality, P is performance, and E is an expectation.

In a traditional manufacturing environment, conformance to specifications and delivery are the common quality items that are measured and tracked. Often, lots are rejected because they don't have the correct documentation supporting them. Quality in manufacturing, then, is conforming product, delivered on time, and having all the supporting documentation. In design, quality is measured as consistent conformance to customer expectations.

The expected performance is actually "what this design can do for me" in the eyes of customers. The American Society for Quality (ASQ) defines quality as a subjective term for which each person has his or her own definition. In technical use, *quality* can have two meanings: (1) it represents the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; or (2) it describes a product or service free of deficiencies. By examining ASQ's definition, we see that "on its ability to satisfy stated or implied needs" means that a product or service should be able to deliver potential customer needs; we call it "doing the right things." And "free of deficiencies" means that the product or service can deliver customer needs consistently. We can call this "doing things right all the time." Several concepts that are associated with quality are defined below (see http://www.praxiom.org/iso-definitions.htm).

- *Quality system:* the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
- *Quality policy:* the overall intentions and direction of an organization with respect to quality as established by management with executive responsibility.
- *Quality management:* includes all the activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance, and quality improvement.
- *Quality audits:* a systematic independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
- *Quality control:* a set of activities or techniques whose purpose is to ensure that all quality requirements are being met. To achieve this purpose, processes are monitored and performance problems are solved.
- *Quality improvement:* anything that enhances an organization's ability to meet quality requirements.
- *Quality assurance:* a set of activities whose purpose is to demonstrate that an entity meets all quality requirements. Quality assurance activities

are carried out to inspire the confidence of both customers and managers, confidence that all quality requirements are being met.

- *Quality planning:* a set of activities whose purpose is to define quality system policies, objectives, and requirements, and to explain how these policies will be applied, how these objectives will be achieved, and how these requirements will be met. It is always future oriented. A quality plan explains how you intend to apply your quality policies, achieve your quality objectives, and meet your quality system requirements.
- *Quality record:* contains objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.
- *Quality requirement:* a characteristic that an entity must have. For example, a customer may require that a particular product (entity) achieve a specific dependability score (characteristic).
- *Quality surveillance:* a set of activities whose purpose is to monitor an entity and review its records to prove that quality requirements are being met.

1.3 QUALITY OPERATING SYSTEM AND THE DEVICE LIFE CYCLE

To deliver a high-quality medical device, we need a system of methods and activities that can provide an overarching structure to plan and develop the product successfully. Such a system, called a *quality operating system*, includes all the planned and systematic activities performed within the system that can demonstrate with confidence that the device will fulfill the requirements for quality. Figure 1.1 depicts a graphical flow of a typical product development life cycle that encompasses the life cycle from ideation through to phaseout or retirement. Below we enumerate the life-cycle stages as vetted with some DFSS concepts. The life cycle in Figure 1.1 will later be married with the famous waterfall design process of a medical device with design control depicted in Figure 1.2.

Design controls is U.S. Food and Drug Administration (FDA) terminology for a product design and development process. Design controls comprise an interrelated set of practices and procedures that are incorporated into the medical device design and development process, a system of checks and balances. The objective is to induce a systematic approach that exhibits deficiencies in design input requirements, and discrepancies between the proposed designs and requirements are made evident and corrected earlier in the design and development process. 21 CFR 820.30 describes what is needed but stops short of defining the "how to," a gap that is well filled by this book. Design controls as expressed in the life-cycle stages depicted here together with six sigma design principles, tools, and methods (collectively known as design for

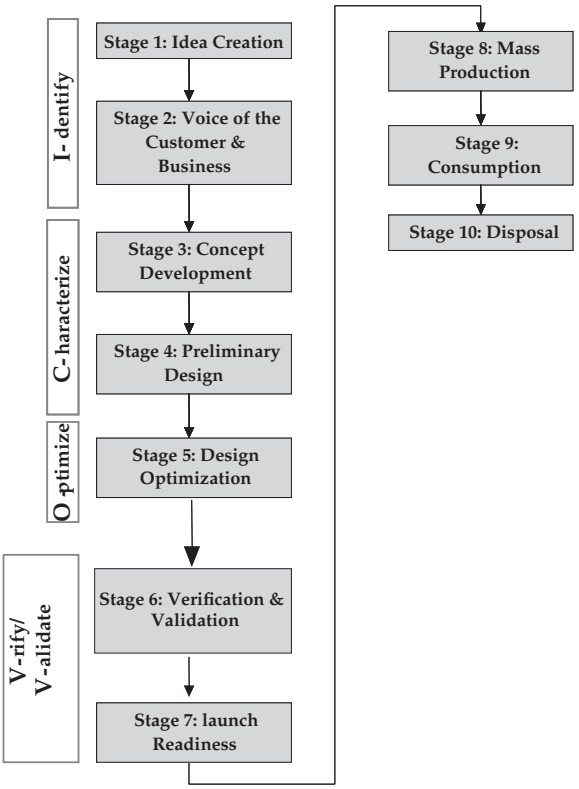

Figure 1.1 Medical device life cycle.

six sigma) constitute an insurance policy that the design transferred to production will translate into a device that exceeds user expectations while satisfying user requirements. In practice, DFSS provides managers and designers with improved visibility of the design process decision making. With improved visibility, managers are empowered to direct the design process more effectively: that is, to prevent problems earlier, and if necessary, to make educated corrective decisions and adjust resource allocations. Design teams benefit both by enhanced understanding of the degree of conformance of a design to user and patient needs, and by improved communications and coordination among all stakeholders of the process.

1.3.1 Stage 1: Idea Creation

The need for a new device can arise from newly emerged needs, R&D (research and development) ideation, benchmarking, technology road maps, and/or multigenerational plans (Chapter 6). New processes often come about because of "revolution," not "evolution." For example, when a new management team

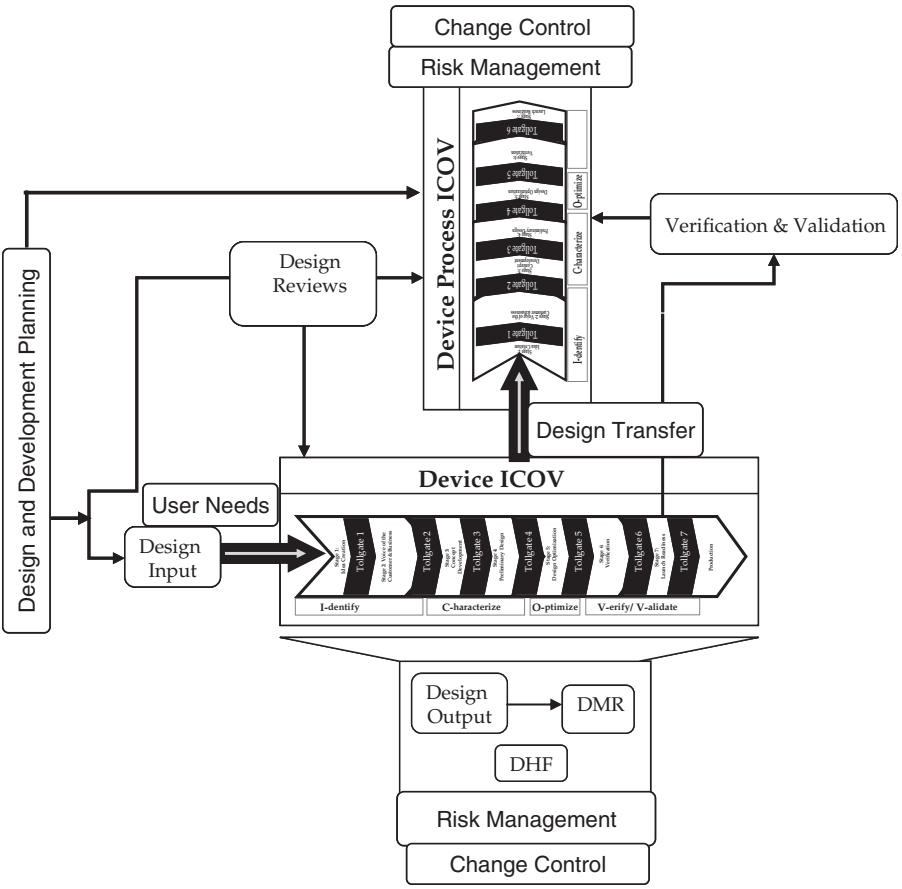

Figure 1.2 Design process with medical device design controls.

is brought in and they staff the organization with knowledgeable people to execute the new strategies and methods, often, the switching costs are huge and it takes time for the new process to start delivering benefits. If the legacy team had been able to evolve slowly, the change brought on by the new team is a revolution. It is the premise of this book that based on performance metrics and benchmarking, natural evolution via DFSS deployment can provide process redesign that is manageable and controllable.

1.3.2 Stage 2: Voice of the Customer and Business

Customer and business requirements must be studied and analyzed in the second stage even under a redesign environment. We need to understand the key functional requirements (in a solution-free environment) which will fulfill the stated or implied needs of both external and internal customers (business).

We also need to understand the relationships between the voice of the customer, the voice of regulatory bodies in the countries where the device will be sold, and the voice of the business. The quality function deployment house of quality is an ideal method for this purpose (see Chapter 8).

1.3.3 Stage 3: Concept Development

Concept development is the third stage in the medical device life cycle. In this stage, concepts are developed to fulfill the functional requirements obtained from the preceding stage. This stage of the life-cycle process is still at a high level and remains solution-free; that is, the design team is able to specify what needs to be accomplished to satisfy the customer wants, not how to accomplish these wants. The strategy of the design team is to create several innovative concepts and use selection methodologies to narrow down the choices. At this stage we can highlight the Pugh concept selection method (Pugh, 1996), summarized in Figure 1.3.

The method of controlled convergence was developed by Stuart Pugh (1991) as part of his solution selection process. Controlled convergence is a solution iterative selection process that allows alternate convergent (analytic) and divergent (synthetic) thinking to be experienced by the service design team. The method alternates between generation and convergence selection activities.

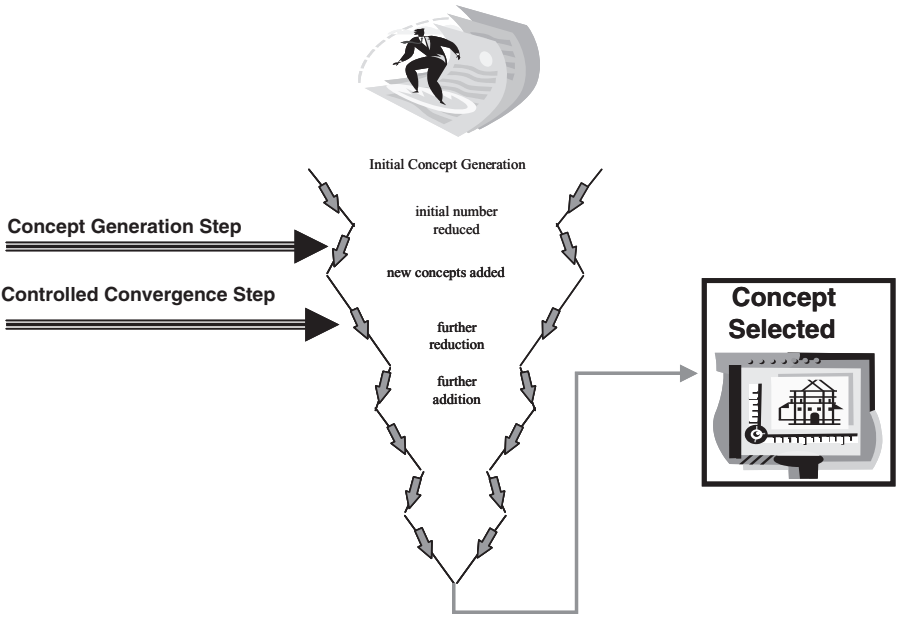

Figure 1.3 Pugh phased innovation.

Tools such as TRIZ [theory of Russian inventive science, also known as TIPS (theory of inventive problem solving)] and the morphological matrix are better suited to creativity, while the Pugh selection matrix helps with the critical selection. TRIZ is explored in Chapter 10.

1.3.4 Stage 4: Preliminary Design

In stage 4, the prioritized functional requirements must be translated into design parameters with detail specifications. Appropriate tools for this purpose are QFD (Chapter 8) or axiomatic design (Chapter 9).

A preliminary design, which could consist of a design structure (architecture or hierarchy) with subsystem requirements flow-down, should be developed in this phase. QFD (Chapter 8) and functional modeling (Chapter 9) are very beneficial in this stage. Design targets for reliability, quality, process ability, and ease are established in stage 4. When one potential design solution has been selected, the team can begin to focus on the specific failure modes of that design using a design failure modes and effects analysis. Concurrently, from all of these design requirements the first elements for inclusion on the design scorecard (Chapter 13) can be identified and recorded.

1.3.5 Stage 5: Design Optimization

In stage 5 the design team will ensure that the final design matches the customer requirements that were identified in stage 2 (capability flows up to meet the voice of the customer). There are techniques [DFX (Chapter 12), FMEA (Chapter 11)] that can be used at this point to ensure that the design cannot be used in a way that was not intended, cannot be processed or maintained incorrectly, or that if there is a mistake, it will be obvious immediately. A final test plan is generated to assure that all requirements are met at six sigma level by the pilot or prototype that is implemented or built in the next stage.

In stage 5, detailed designs are formulated and tested either physically or through simulation. Functional requirements are flowed down from system level into subsystem design parameters using transfer functions (Chapter 13), functional modeling (Chapter 9), and design of experiments (Chapter 14). Designs are made robust to withstand the noise introduced by external uncontrollable factors (Chapter 15). All of the activities in stage 5 should result in a design that can be produced in a pilot or prototype form.

1.3.6 Stage 6: Verification and Validation

Test requirements and procedures are developed and the pilot is implemented and/or the prototype is built in this stage. The pilot is run in as realistic a setting as possible, with multiple iterations and subjected to as much noise as possible in an environment that is as close as possible to its final usage

conditions. The same philosophy applies to the testing of a prototype. The prototype should be tested at the extremes of its intended range and sometimes beyond. To the extent possible or allowed by regulation, simulation should replace as much testing as is feasible in order to reduce cost and risk. In the medical device industry, a distinction is made between design verification and validation. *Design verification* is a process whose purpose is to examine design outputs and to use objective evidence to confirm that outputs meet input requirements. *Design validation* is a process whose purpose is to examine devices and to use objective evidence to confirm that these products meet user needs. See Figure 1.2 for more clarification.

In general, the results of pilot or prototype testing allows the design team the opportunity to make final adjustments or changes in the design to ensure that the product, service, or business process performance is optimized to match customer expectations. In some cases only real-life testing can be performed. In this situation, design of experiments is an efficient way to determine if the desired impact is created and confirmed.

1.3.7 Stage 7: Launch Readiness

Based on successful verification and validation in a production environment, the team will assess the readiness of all the process infrastructure and resources. For instance, have all standard operating procedures been documented and personnel trained in the procedures? What is the plan for process switchover or ramp-up? What contingencies are in place? What special measures will be in place to ensure rapid discovery? Careful planning and understanding of the desired behavior are paramount to successful transition from the design world into the production environment. In Chapter 18 we describe in detail all the requirements, through best-demonstrated practices, for successful design transfer to production and service.

1.3.8 Stage 8: Mass Production

In this stage, if the team has not already begun implementation of the design solution in the production environment, the design team should do so now. The product will be produced and shipped to the market. Some parts or subassemblies might be produced by suppliers. During production it is very important that the manufacturing process be able to function consistently and free of defect, and all parts and subassemblies supplied by suppliers should be consistent with quality requirements.

For quality assurance at this stage, the key task is to ensure that the final design is in conformance with design requirements. That is, all products, together with their parts and subassemblies, should conform to their design requirements; they should be interchangeable and consistent. The quality methods used in this stage include statistical process control, quality standard

and acceptance inspection for suppliers, and production troubleshooting and diagnosis methods.

1.3.9 Stage 9: Consumption

During this stage, devices are consumed by customers. This stage is really the most important to consumers, for it is the consumer who will form opinions of the design and brand name. When customers encounter problems such as defects, warranty, and service when using a design during consumption, it is important to keep the design in use and the customer satisfied.

For quality assurance in this stage, it is impossible to improve the quality level for designs already in use because they are already out of the hands of the producer. However, a good warrantee and service program will certainly help to keep the design in use by repairing defective units and providing other after-sale services. Usually, warranty and service programs are very expensive compared to doing things right the first time. Warranty and service programs can also provide valuable information for the quality improvement of future production and device design.

1.3.10 Stage 10: Disposal or Phaseout

Eventually, all products and services become obsolete, replaced by either new technologies or new methods. Also, the dynamic and cyclical nature of customer attributes dictates continuous improvement to maintain adequate market share. Usually, it is difficult to turn off the switch, as customers depend on a device differently. Just look at dialysis machines: One cannot just convert to a single new dialysis process; there must be a coordinated effort and change management is often required to convince customers to shift to the new device.

1.4 EVOLUTION OF QUALITY

The earliest Egyptian, Mayan, and Aztec societies left archeological evidence of precision and accuracy nearly unmatched today. Following these societies we entered into an extended period of apprenticeship in which we developed conformance to customer requirements with never more than one degree of separation between the producer and the customer. During the industrial revolution, societies began to separate producers from consumers, and this led to the discovery and development of quality methodologies to improve the customer experience. These practices evolved around product-based processes during this era of globalization.

There are three components that drive the evolution of quality: knowledge, technology, and resources. Basic knowledge of quality philosophy, methods,

and tools precedes the automation of these tools via technology and is followed by general awareness and adoption by practitioners.

In the early days of the pioneering Walter A. Shewhart, slide rules were the prevalent technology, and even the simplest calculations were tedious. The high level of effort required for calculations resulted in simplification of statistical process control to use $\bar{X}$- and R-charts and prevented rapid adoption of statistical process control. Today, we have mature knowledge with automated data capture systems and the ability to analyze large data sets with personal computers and statistical software. Today's resources have higher math skills than the average person had in Shewhart's time, and the penetration of quality methods has expanded into customer-touching support processes as well as product-based processes. The adoption of enabling processes such as human resources, supply chain, legal, and sales, although analogous to customer-touching processes, is weak, due to the perceived cost–benefit deficit and a lack of process-focused metrics in these processes.

Let us look at an abbreviated chronological review of some of the pioneers who added notably to the knowledge of quality. Much of quality evolution has occurred in the following five disciplines: (1) statistical analysis and control, (2) root-cause analysis, (3) total quality management, (4) design quality, and (5) process simplification. The earliest evolution began with statistical analysis and control, so we start our chronology there.

1.4.1 Statistical Analysis and Control

In 1924, Walter A. Shewhart introduced the first application of control charting to monitor and control important production variables in a manufacturing process. This charting method introduced the concepts of special and common cause variation. He evolved his concepts and in 1931 published *Economic Control of Quality of Manufactured Product*, which brought together successfully the disciplines of statistics, engineering, and economics, and with this book, Shewhart became known as the father of modern quality control. Shewhart also introduced plan–do–study–act (Shewhart cycle), later made popular by Deming as the PDCA cycle.

In 1925, Sir Ronald Fisher published *Statistical Methods for Research Workers* and introduced the concepts of randomization and analysis of variance (ANOVA). Later in 1925 he published *Design of Experiments*. Frank Yates, an associate of Fisher, contributed Yates' standard order for ANOVA calculations. In 1950, Gertrude Cox and William Cochran coauthored *Experimental Design*, which became the standard of the time. In Japan, Genechi Taguchi introduced orthogonal arrays as an efficient method for conducting experimentation within the context of robust design. He followed this up in 1957 with the book *Design of Experiments*. Taguchi's robustness methods have been used in product development since the 1980s. In 1976, Douglas Montgomery published *Design and Analysis of Experiments*, followed by George

Box, William Hunter, and Stuart Hunter's *Statistics for Experimenters* in 1978.

1.4.2 Root-Cause Analysis

In 1937, Joseph Juran introduced the Pareto principle as a means of delineating root causes. In 1943, Kaoru Ishikawa developed the cause-and-effect or fishbone diagram. The use of multivariable charts was promoted first by Len Seder of Gillette Razors in 1949 and then service-marked by Dorian Shainin, who added it to his Red X tool box, which became known as the Shainin techniques in the period 1951 through 1975. Root-cause analysis as known today relies on seven basic tools: the cause-and-effect diagram, check sheet, control chart (special cause versus common cause), flowchart, histogram, Pareto chart, and scatterplot (Figure 1.4).

1.4.3 Total Quality Management

The integrated philosophy and organizational alignment for pursuing the deployment of quality methodologies is often referred to as total quality management (TQM). Its level of adoption has often been related directly to the tools and methodologies referenced by the leaders who created the methods and tools as well as the perceived value of adopting them. Armand V. Feigenbaum published *Total Quality Control* in 1951 while at MIT pursuing his doctorate. He later became head of quality for General Electric and interacted with Hitachi and Toshiba. His pioneering effort was associated with the translation into Japanese of his 1951 book *Quality Control: Principles, Practices and Administration* and his articles on total quality control.

Joseph Juran followed closely in 1951 with the *Quality Control Handbook*, the most comprehensive "how-to" book on quality ever published. At this time, W. Edwards Deming was gaining fame in Japan following work for the U.S. government in the Census Bureau developing survey statistics, and pub-

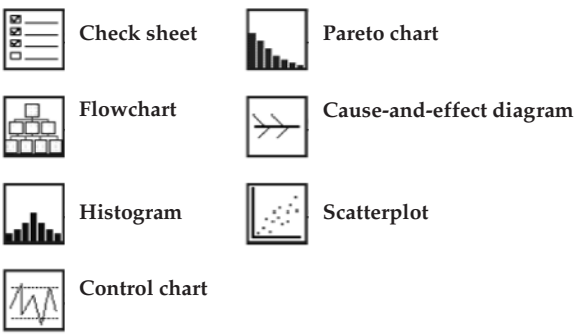

Figure 1.4 Seven basic quality tools.

lished his most famous work, *Out of the Crisis*, in 1986. Deming had associations with Walter Shewhart and Sir Ronald Fisher and has become the most notable TQM proponent. Deming's basic quality philosophy is that productivity improves as variability decreases and that statistical methods are needed to control quality. He advocated the use of statistics to measure performance in all areas, not just conformance to design specifications. Furthermore, he thought that it is not enough to meet specifications; one has to keep working to reduce the variations as well. Deming was extremely critical of the U.S. approach to business management and was an advocate of worker participation in decision making. Kaoru Ishikawa then became noticed for his development of quality circles in Japan and published the *Guide to Quality Control* in 1968. The last outstanding pioneer is Philip Crosby, who in 1979 published *Quality Is Free*, in which he focused on the "absolutes" of quality and the basic elements of improvement and the pursuit of "zero defects."

1.4.4 Design Quality

From a regulatory perspective, 21 CFR Part 820 is a high-level description of design controls that will assure design quality. However, adherence to regulations implies only the bare minimum of what needs to be done. The quality of work and how to do it can be assured only via a rigorous process such as design for six sigma, the subject of this book.

Design quality includes philosophy and methodology. The earliest contributor in this field was the Russian Genrich Altshuller, who provided us with the theory of inventive problem solving (TRIZ or TIPS) in 1950. TRIZ is based on inventive principles derived from a study of over 3.5 million of the world's most innovative patents and inventions. TRIZ is a revolutionary way of solving problems systematically based on science and technology. TRIZ helps organizations use the knowledge embodied in the world's inventions to develop elegant solutions to the most difficult design and engineering problems quickly, efficiently, and creatively. The next major development was quality function deployment (QFD), promoted in Japan by Yoji Akao and Shigeru Mizuno in 1966 but not Westernized until the 1980s. Their purpose was to develop a quality assurance method that would design customer satisfaction into a product before it was manufactured. Prior quality control methods were aimed primarily at fixing a problem during or after manufacturing. QFD is a structured approach to defining customer needs or requirements and translating them into specific plans to produce products or services to meet those needs. The *voice of the customer* is the term used to describe these stated and unstated customer needs or requirements.

In the 1970s Taguchi promoted the concept of the quality loss function, which stated that any deviation from nominal was costly and that by designing with the noise of the system the product would operate within, one could optimize designs. Taguchi packaged his concepts in the methods named after him: robust design and quality engineering.

The last major development in design quality was that of Nam P. Suh and his axiomatic design approach. Axiomatic design is a principle-based method that provides a designer with a structured approach to design tasks. In this approach, design is modeled as mapping between different domains. For example, in the concept design stage, it could be a mapping between customer attribute domain and the design function domain; in the product design stage, it is a mapping from the function domain to the design parameter domain. There are many possible design solutions for the same design task. However, based on its two fundamental axioms, axiomatic design method developed many design principles to evaluate and analyze design solutions and gave designers directions by which to improve designs. The axiomatic design approach can be applied not only in engineering design but also in other design tasks, such as in organization systems. El-Haik (2005) integrated robust design and axiomatic design in a framework called *axiomatic quality*. Design quality is the focus of this book.

1.4.5 Process Simplification

Lately, "lean" has become a topic of great interest. The pursuit of the elimination of waste has led to several quality improvements. The earliest development was poka-yoke (mistake-proofing), developed by Shigeo Shingo in Japan in 1961. The essential idea of poka-yoke is to design processes such that mistakes are impossible to make or at least are easily detected and corrected. Poka-yoke devices fall into two major categories: prevention and detection. A prevention device affects a process such that it is impossible to make a mistake. A detection device signals the user when a mistake has been made so that the problem can be corrected quickly. In 1970, Shingo, developed single minute exchange of die (SMED). This trend toward "lean" has also seen more systemwide process mapping and value analysis, which has evolved into value stream maps.

1.4.6 Six Sigma and Design for Six Sigma

The initiative known as six sigma[1] follows in the footsteps of all the techniques described above. Six sigma was conceptualized and introduced by Motorola in the early 1980s. It spread to Texas Instruments and Asea Brown Boveri, then to Allied Signal and to General Electric in 1995. It has been enabled by the emergence of the personal computer and by statistical software packages such as Minitab, SAS, BMDP, and SPSS. It combines each of the elements of process management and design: define–measure–analyze–improve–control and design for six sigma. We discuss these in detail in later chapters.

[1]The word *sigma* refers to the Greek letter σ, used by statisticians to measure variability. As the numerical levels of σ increase, the number of defects in a process fall exponentially. Six sigma design is the ultimate goal since it means that if the same task were performed 1 million times, there would be only 3.4 defects, assuming normality.

Design for six sigma (DFSS; see Chapters 5 to 7) is a disciplined methodology that embeds customer expectations into the design, applies the transfer function approach to ensure that customer expectations are met, predicts design performance prior to the pilot phase, builds into the design performance measurement systems with scorecards to ensure effective ongoing process management, leverages a common language for design, and uses tollgate reviews to ensure accountability.

DFSS is a disciplined and rigorous approach to service, process, and product design through ensuring that new designs meet customer requirements prior to launch. It is a design approach that ensures complete understanding of development steps, capabilities, and performance measurements by using scorecards and tollgate reviews to ensure accountability of design stakeholders, black belts, project champions, deployment champions, and the rest of an organization.

DFSS may be used to design or redesign a product or service. The expected process sigma level for a DFSS product or service is at least 4.5 but can be 6 sigma or higher, depending on the designed entity. The production of such a low defect level from product or service launch means that customer expectations and needs must be understood completely before a design can be operationalized. That is, quality is defined by the customer. Our DFSS approach has the following four phases:

1. Identify customer wants and design inputs and map them to design outputs.
2. Characterize the medical design entity and develop its conceptual structure.
3. Optimize the medical device entity in its environment of use.
4. Verify/validate the medical device entity that delivers its functional outputs. This includes validation to customer wants.

Figure 1.5 illustrates the the DFSS *Identify–characterize–optimize–verify/validate* (ICOV) *process* over the device life cycle shown in Figure 1.1.

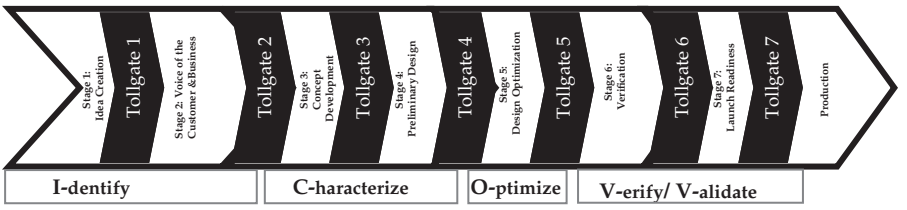

Figure 1.5 DFSS ICOV process.

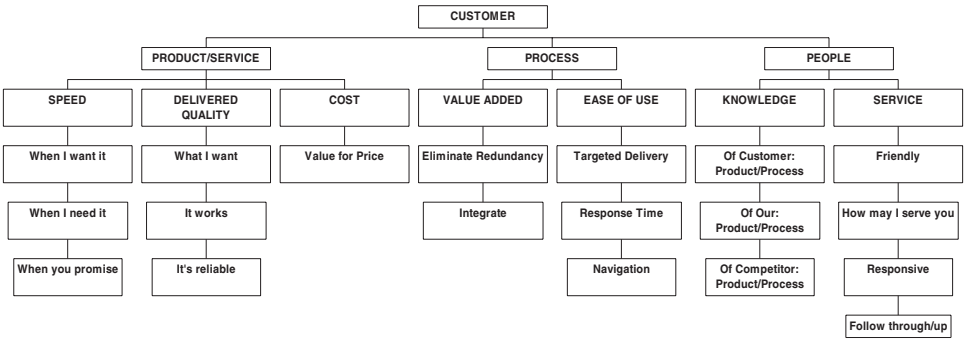

Figure 1.6 Customer experience channels.

1.5 BUSINESS EXCELLENCE: A VALUE PROPOSITION

At the highest level, business excellence is featured by good profitability, business viability, and growth in sales and market share based on quality (Peters and Waterman, 1980). Achieving design excellence is the common goal for all business leaders and their employees. To achieve design excellence, design quality itself is not sufficient; *quality* has to be replaced by *whole quality*, which includes quality in business operations as well, as shown in Figure 1.6. To understand business excellence, we need to understand business operation and other metrics in business operation, which we cover in the next section.

1.5.1 Business Operation Model

Figure 1.7 shows a typical high-level business operation model for a manufacturing company. For companies that are service-oriented, the business model

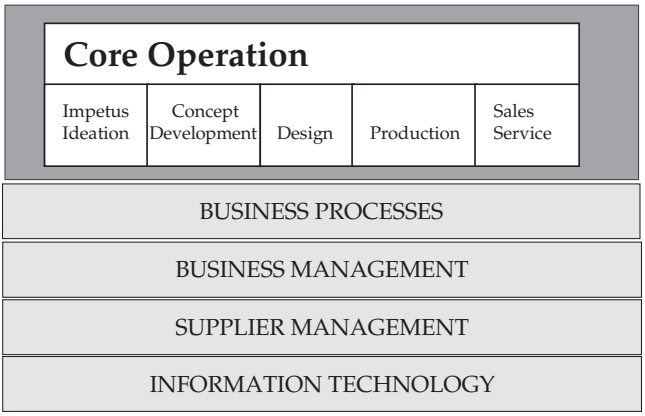

Figure 1.7 Typical business operation model.

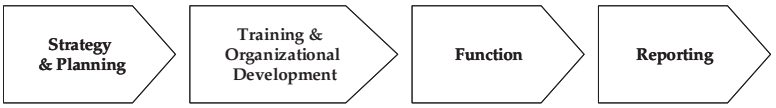

Figure 1.8 Business functional core operation and auxiliary requirements model.

could look somewhat different. However, for every company there is always a *core operation* and a number of other enabling business elements. The core operation is the collection of all activities (processes and actions) that provide service designs to customers. For example, the core operation of Federal Express is to deliver packages around the world, and the core operation of Starbucks is to provide coffee service all over the world. Core operations extend across all activities in the design life cycle.

For a company to operate, the core operation alone is not enough. Figure 1.7 listed several other typical elements that are needed to make a company fully operational, such as business process and business management. The success of a company depends on the success of all aspects of business operation. In addition to the structure depicted in Figure 1.7, each function also has a life cycle of its own, as shown in Figure 1.8. Each of the blocks from Figure 1.7 can be dropped into the function chevron of Figure 1.8, and then each function requires strategy and planning, training and organizational development, and reporting to support its core function.

Before six sigma, quality was narrowly defined as the quality of the design that a company provided to external customers; therefore, it relates to the core operation only. Clearly, from the point of view of a business leader, this "quality" is only part of the story, because other critical factors of business success, such as cost, profit, time to market, and capital acquisition, are also related to other aspects of business operation.

The key difference between six sigma and all quality systems and methods developed previously is that six sigma is a strategy for the *whole quality* (every quality dimension concurrently), which is a dramatic improvement for the *whole business operation*. Notice that although we focus on the first seven stages of the medical device life cycle, the concepts are applicable to the remaining stages as well.

In the following sections we show that improving the whole quality will lead to business excellence because that involves improving all major performance metrics of business excellence, such as profit, cost, and time to market.

1.5.2 Structure of the Medical Device Quality Function

In this section we provide a current-state critique of the medical device industry's quality, regulatory, and compliance functional requirements and provide suggestions for improvement. We open with a definition of ideal functional structure to help companies to set up their internal functions and organization

architecture for design excellence and regulatory compliance based on best practices. We believe that an ideal organization should have the following structure:

1. If a medical device company has many divisions and a corporate headquarters, the corporate staff should have oversight of the quality and regulatory compliance activities of the divisions. The FDA will hold all of the divisions accountable for fixing discrepancies found at any location. Corporate staff needs the authority to institute corrective and preventive actions throughout the company. Many companies have organized their quality, regulatory, and compliance functions locally by manufacturing site, whereas others have corporate oversight for these functions. In large companies, the quality system used at any manufacturing site should have a definite mechanism for assuring that the site complies with corporate quality policies. The FDA will hold headquarters management responsible and accountable for site failures. Corporate management reviews should include assessments of site quality functions. The most effective quality assurance and regulation assurance groups have a major role in establishing, maintaining, and continuously improving metrics and for monitoring and reporting quality data. The key areas are corrective action/preventive action (CAPA), complaints, regulations, field actions, change management, risk management, and assurance of management functions. Quality engineering for research and development should also be extended beyond the traditional assurance function, a gap that is nicely filled by design for six sigma.
2. The most common functional responsibilities are:
   - Quality personnel have responsibility for CAPA management, document control, equipment calibration, external audits, final inspection, incoming inspection of raw material, in-process inspection, internal quality audits, management representative, product and GMP (good manufacturing practice) audits, product complaint management, product releases, process validation, risk management, sterilization, supplier program management, and supplier qualification.
   - Regulatory personnel have responsibility for adverse-event reporting, annual product releases, facility registration and licenses, production registration and certification, product regulatory submissions, and recalls.
   - Compliance personnel have responsibility for the business code of conduct, environmental program management, health and safety program management, preventive maintenance, and training.
3. The top officials for quality, regulatory, and compliance concerns should be at the vice presidential level, equal in seniority to other officials in staff positions. There is a wide variation as to the title of the top official for the quality, regulatory, and compliance functions. The most common

title is vice president or senior vice president. The major issue here is that the top quality assurance, regulatory assurance, and compliance person is at the same level as the top finance, marketing, R&D, and other executives. It is important that the quality organization have titles similar to those used in production and manufacturing. These groups should be viewed as peers. Senior vice president is appropriate in larger companies.

4. All companies need to measure the *cost of poor quality* (the cost of internal and external failures, appraisal, and preventive action) and invest sufficient resources in preventive action, but the majority of companies are not doing so. The cost of poor quality is a metric that all good companies should utilize. Companies could not measure effectiveness and efficiency without it. It must include both the price of conformance and the price of nonconformance. It can be just as important to lower the price of conformance as to lower the price of nonconformance. The price of nonconformance was one of the four absolutes that Phil Crosby promoted in his fundamental overview of quality, which is still relevant today. When nothing bad is happening, how do responsible functions convince management that it is because of the good quality system that is in Hace? They need to show how good quality has increased market share, decreased inspection times, reduced nonconformities, increased yields, and reduced the cost of products purchased.
5. Companies need to embrace risk management and utilize its concepts throughout their quality, regulatory, and decision-making processes. The majority of companies use risk management principles throughout their quality system: design control, CAPA, complaint management, management review, and process control. Risk management principles need to be utilized throughout the life cycle of a device (Figure 1.1), as it is a dynamic process, not simply a design control tool. Using risk to help make better decisions will assure that resources are spent wisely—but only if quality is part of our risk decisions, not just cost–benefit issues.

   Risk management is huge. Clearly, it is not just needed simply for design control. The FDA stated in the QSR preamble that risk management should also be used in CAPA. It is also essential in production and process control. It is worth noting that the FDA used the word *risk* close to 50 times in the QSR preamble.

Having separate functions for the quality, regulatory, and compliance functions is normal. The management representative should have a mechanism to be informed of all quality issues, no matter what department he or she is part of. It is also important to assure that quality remains independent of production (or R&D in design-only) facilities. From a reporting structure point of view, variant forms are noted. Many companies have a reporting structure with quality, regulatory, and compliance groups reporting to a single point of

control. Others have independent quality, regulatory, and compliance groups reporting structures. There are as many ways to develop a reporting structure as there are companies. The goal is to have a structure that allows effective, efficient, and timely oversight and control. The most effective companies have an independent facility for quality, regulatory, and compliance groups, with a common corporate oversight group that establishes and maintains consistency and tackles common issues when they arise. Most companies have their quality, regulatory, and compliance officials report directly to the president. Companies whose quality and compliance functions do not report to the president are often companies that face compliance actions by the FDA. It is essential that quality personnel report to the CEO or president. This assures independence as well as access to resources. A majority of firms had their senior quality, regulatory, and compliance functions report periodically to the board of directors with regular updates. Since the board of directors can also be held responsible for quality system deficiencies, they should be aware through management reviews of quality problems.

All world-class quality companies empower the quality and regulatory functions to stop production or initiate a recall. This is a positive trend that should be reinforced. From an authority perspective, some medical device companies have their regulatory personnel responsible for product submissions, compliance to QSR, and ISO 13485; others have their regulatory personnel responsible only for product registrations and licenses. Depending on the size and structure of the organization, this can be combined or separated. In either case, personnel must communicate and coordinate their activities. In our view, to be effective, regulatory and quality responsibility are almost inseparable functions that need to be tightly coordinated. We are seeing more and more separation of the quality and regulatory functions. Unless a company is quite small, we would not recommend combining responsibilities as it spreads management too thin.

Commitment to quality varies by company. A few strive to be the best in an industry, others wants to assure product safety and efficacy and essential quality system compliance, and some want only to meet the requirements minimally. But for the very best outcome, all companies should strive to be "state of the art," which starts with design and product development.

Best-in-class and world-class efforts should not be fell to be beyond many companies' ability to achieve. The investment is small to moderate in terms of people, resources, and capital. Focus is critical. To be the best in the business and an attractive place to work are attractive goals for both employees and managers. The goal for products, processes, and systems should be six sigma perfection. A company that strives to be the best in quality shows a true understanding of the reason for having a quality system. Six sigma perfection may be a long-term objective, but moving in that direction is why companies control design, manufacturing and changes, and utilize a feedback loop (CAPA). In the medical device business, laggards who strive only to meet

minimal requirements often suffer regulatory violations and customer dissatisfaction.

The brutal facts are that only a small percentage if companies are among the best. Most are in the average competently range, and a few are not effective at all. The problem is that many of the average competent companies fail to recognize and accept their true status and therefore fail to make the investments (in people, infrastructure, systems) required to reach and maintain the state of the art, let alone continuous improvement. If you believe that your quality system needs an overhaul, take the time to look at your policies, procedures, and actual practices as part of a failure investigation. Process-map your systems and your processes. Use technical writers to write your procedures to assure that they are concise, well written, and not ambiguous. Make sure that your mapping for each process or subsystem flows together to form a complete quality system. Time spent in developing systems and processes that are complete and easy to follow, implement, and comply with is time well spent.

1.5.3 Quality and Cost

Given that you have a salable product or service, low cost is related directly to high profitability. Cost can be divided roughly into two parts: life-cycle costs related to all designs offered by the company, and the cost of running the supporting functions within the company, such as various enabling operations-related departments. For a particular product or service, life-cycle cost includes production and service cost, plus the cost for design development.

The relationship between quality and cost is rather complex; in this context the quality referred to is the design quality, not the *whole quality*. This relationship is very dependent on what type of quality strategy is adopted by a particular company. If a company adopted a quality strategy focused heavily on the downstream end of the design life cycle (i.e., firefighting, rework, and error corrections), that quality is going to be very costly. If a company adopts a strategy emphasizing upstream improvement and problem prevention, improving quality could actually reduce the life-cycle cost because there will be less rework, less recall, less firefighting, and therefore less design development cost. In a service-based company, it may also mean fewer complaints, higher throughput, and higher productivity. For more discussion of this topic, see Chapter 3 of Yang and El-Haik (2003).

If we define quality as whole quality, higher whole quality will definitely mean lower total cost. Because whole quality means higher performance levels of all aspects of business operation, it means high performance of all supporting functions, high performance of production system, less waste and higher efficiency. Therefore, it will definitely reduce business operation cost, production cost, and service cost without diminishing the service level to the customer.

1.5.4 Quality and Time to Market

Time to market is the speed in introducing new or improved products and services to the market. It is a very important measure for competitiveness in today's marketplace. For two companies that provide similar designs with comparable functions and price, the company with the faster time to market will achieve a tremendous competitive position. The first provider sets a psychological effect that will be very difficult for latecomers to overcome.

Many techniques are available to reduce time to market, such as:

- *Concurrency:* encouraging multitasking and parallel working
- *Complexity reduction* (Suh, 2001; El-Haik, 2005)
- *Project management:* tuned for design development and life-cycle management

In the six sigma approach and whole quality concept, improving the quality of managing the design development cycle is a part of the strategy. Therefore, improving whole quality will certainly help to reduce time to market.

1.6 SUMMARY

Quality as a characteristic refers to the perception of the degree to which the product or service will meet customers' expectations. Quality has no specific meaning unless related to a specific function or measurable characteristic. The best quality assurance strategy is "do the right things, and do things right all the time." "Do the right things" means that we have to design the best product or service for customers' needs at a cost that represents value to them. "Do things right all the time" means that products and services are performing consistently and customers are satisfied at all times. If we miss any of that, quality will be missed as well.

Quality has evolved over time from the early 1920s, when Shewhart introduced the first control chart, through the transformation of Japan from the 1950s to the late 1980s, when six sigma came on the scene. Six sigma, design for six sigma (DFSS), and lean have now been merged and enabled by personal computers and statistical software to provide easy-to-use and high-value methodologies to attack waste and reduce variation on both new designs and existing processes in order to fulfill customer requirements.

Six sigma design principles, tools, and methods (collectively known as design for six sigma) provide an insurance policy for the design transferred to production, which will be translated into a device that exceeds user expectations while satisfying user requirements. In other words, DFSS as a design

quality tool kit provides managers and designers with improved visibility of design process decision making. With improved visibility, managers are empowered to direct the design process more effectively: that is, to prevent problems earlier, and if necessary, to make educated corrective decisions and adjust resource allocations.